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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,375	10/24/2003	Yong K. Cho	P11461.00	1669

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EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,375	CHO ET AL.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,23-50,52,62-79,81 and 91-93* is/are rejected.

7)☒ Claim(s) *18-22,51,53-61,80 and 82-90* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/14/05, 5/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because of the reasons given in the included PTO-948 form. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 76 is objected to because of the following informalities: the claim reads "the computer readable medium of claim 36" in line 1 of the claim. The examiner, for

the purpose of examination, assumes the applicant to mean "the method of claim 36." Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 48, 50 and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 48 and 50 recite the limitation "the x number of cardiac cycles" in line 1 of the claim. Claim 79 recites the same limitation in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5, 7, 14-15, 23, 34-36, 45, 63-65 and 92-93 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonnet (U.S. 6,574,507). Regarding claims 1

and 14, Bonnet discloses (column 2, lines 61-68; column 3, lines 1-3) "an active implantable medical pacemaker device allowing for the treatment by increased cardiac electrostimulation of the sleep apnea syndrome in a patient i.e., including: means for measuring the respiratory activity of the patient; means for analyzing and determining an occurrence of an apnea in response to the measured respiratory signal; and means for delivering an SAS (syndrome of sleep apnea) stimulation, controlled by the analyzing means, so as to apply selectively to the patient an increased cardiac stimulation rate in the event of a detection of an apnea." The examiner considers this to be a detection module for determining the presence of sleep-disordered breathing and a stimulation module for delivering augmentation therapy to cardiac tissue when the detection module indicates a presence of sleep-disordered breathing.

Regarding claims 2-5, 7, 15, 34-35 and 92-93, Bonnet discloses (column 3, lines 5-11) "the respiratory activity measurement means may be a circuit which includes a minute ventilation sensor or a sensor which detects the oxygen saturation of the blood." The device "also includes means for determining a cardiac rate of the patient, including a rate in the absence of a determined apnea, means for determining a state of activity of the patient."

Regarding claim 23, Bonnet discloses (column 9, lines 7-12) "stimulation at the higher rate is applied for a given period of time, for example, sixty seconds and afterwards the device reverts to the former mode of operation, e.g., the lower stimulation frequency. It also should be understood that the increased cardiac stimulation can be applied together with a muscular and/or a neurological stimulation in

response to a determined SAS." The examiner considers this to be a means for determining a cycle length of a sleep-disordered breathing episode, wherein the means for delivering augmentation therapy deliver the therapy for a period of time based on the determined cycle length.

Regarding claims 36, 45 and 63-64, in view of the structure as disclosed by Bonnet, the method of operating or using the device would be inherent because it is the normal and logical means by which the device can be used.

Regarding claim 65, Bonnet discloses (column 9, lines 28-37) "the sensing circuit comprises substantially all of logic and hardware elements required to operate the sensor to sense the parameter and produce output signals corresponding to the sensed parameter, and to deliver a signal utilizable by the main circuit of the pacemaker. The main circuit includes a microprocessor and memory (RAM and/or ROM), as well as conventional latches, registers and power supplies (not shown) for processing the information for the enslavement of the stimulation frequency." The examiner considers this to teach a computer readable medium capable of performing the actions of the above-cited paragraphs.

7. Claims 1-7, 11-17, 23-24, 34-36, 45-50, 52, 62-65, 65, 74-76, 78-79, 81 and 91-93 are rejected under 35 U.S.C. 102(e) as being anticipated by Park et al (U.S. 2003/0153954). Regarding claims 1-2, 4-5, 14-16 and 34-35, Park discloses (paragraphs 0040-0042) "a physiological sensor (106) that senses physical motion or metabolic demand and can be used to detect either a sleeping state or a sleep apnea condition. In one example, an impedance sensor may be used to detect respiration

parameters including, for example, respiration rate and minute volume. In addition to preventing sleep apnea, the cardiac stimulation device (100) may detect respiratory difficulties such as episodes of sleep apnea using the physiological sensor (102) and invoke dynamic overdrive pacing to treat sleep apnea. A system that includes an impedance sensor for sensing respiratory parameters can track respiration to integrate overdrive pacing with periodic breathing. In another embodiment, the cardiac stimulation device may prevent sleep apnea using a tiered therapy including an elevated pacing rate stage, a resynchronization stage, and a dynamic overdrive stage. In the elevated pacing stage, the pacing rate is raised to a preset level or to a level that is a preselected increment over the average rate obtained by monitoring over an extended time. In the resynchronization stage, the pacing rate is slowly reduced to resynchronize with the patient's intrinsic rate or to a preset base rate. In the dynamic overdrive stage, the pacing rate is increased over the intrinsic rate to assure that the pacing rate is at least slightly faster than the intrinsic rate."

Regarding claim 3, Park discloses (paragraph 0044) "various techniques may be used to detect the sleep condition such as sensing of a reduced metabolic demand or physical activity using various physiological or motion sensors, sensing of a reduced heart rate by a cardiac electrical signal sensor."

Regarding claims 6 and 7, Park discloses (paragraphs 0036-0037) the use of sensors to measure blood oxygen and/or blood carbon dioxide concentration.

Regarding claims 11-13, Park discloses (paragraphs 0057-0058) "in one example, intervention treats the sleep apnea condition by dynamic overdrive pacing.

Referring to FIG. 4, a stimulation device (410) electrically couples to a patient's heart (412) using three leads (420, 424, and 430) to electrically communicate signals suitable for delivering multiple-chamber stimulation and shock therapy. The stimulation device couples to an implantable right atrial lead (420) having at least an atrial tip electrode (422) to sense atrial cardiac signals and to supply right atrial chamber stimulation therapy." The examiner considers this to be a stimulation module that provides atrial pacing coupled with the augmentation therapy. The atrial pacing is atrial overdrive pacing, but it also provides atrial coordinated pacing.

Regarding claim 17, Park discloses (paragraph 0101) "method using an automatic stepped increase over a calculated average atrial rate sets and controls overdrive pacing rate based on step increments that may introduce controlled variability into the cardiac rate. In a dual-chamber pacemaker, atrial rate may be monitored beat-for-beat or as an average of a number of beats. Control based on averaged atrial rate prevents premature atrial contractions (PACs) from falsely changing pacing rate." The examiner considers this to be means for calculating a mean heart rate. The means for providing atrial pacing pace the atria at an atrial rate equal to the mean heart rate plus a predetermined value to achieve atrial overdrive pacing.

Regarding claim 23, Park discloses (paragraph 0099) "a method of overdrive pacing based on applying a step increase to a measured atrial rate. The automatic diurnal rate determination method involves iteratively calculating the diurnal base rate as a function of a running average of the sensed heart rate." See Figure 7. The examiner considers this to be means for determining a cycle length of a sleep

disordered breathing episode, wherein the means for delivering augmentation therapy deliver the therapy for a period of time based on the determined cycle length.

Regarding claim 24, Park discloses (paragraph 0098) "the stimulation device can detect a sleeping condition of the patient and initiate a sleep apnea prevention overdrive rate therapy action (612)." The examiner considers this to be means for determining a cycle length of a sleep-disordered breathing episode, wherein the means for delivering augmentation therapy deliver the therapy at a time prior to an onset of sleep-disordered breathing.

Regarding claim 25, Park discloses (paragraph 0069) "Referring again to FIG. 5, an atrial pulse generator (570) and a ventricular pulse generator (572) generate pacing stimulation pulses that are delivered by the right atrial lead (420), the right ventricular lead (430), and/or the coronary sinus lead (424) via an electrode configuration switch (574)." The examiner considers this to be means capable of causing an effective ventricular rate that is greater than the average sleep disorder rate when augmentation therapy is delivered.

Regarding claims 36, 45-46, 49, 52 and 6-64, in view of the structure as disclosed by Park, the method of operating or using the device would be inherent because it is the normal and logical means by which the device can be used.

Regarding claims 47-48, 50 and 76, Park discloses (paragraphs 0046-0047) "the high pacing rate action (206) may last for a selected duration, for example a specified number of cardiac cycles or units of time. In the tiered therapy, resynchronization (208) is executed by gradually reducing the pacing rate by a selected delta rate or interval

until the heart beats at an intrinsic rate or a selected base rate." Park further discloses (paragraph 0095) "the pacing rate may be decreased for each cardiac cycle or may be decreased in steps with the individual steps lasting for a selected number of cardiac cycles. The update atrial rate action 608 resets the pacing rate to the assured overdrive rate if warranted by too frequent inhibited cycles." The examiner considers this to be determining a cycle length of the sleep-disordered breathing, determining a mean heart rate oscillation, and delivering ACP with the augmentation therapy for X cycles. The number of cardiac cycles equates to a time interval that is equal to or greater than the cycle length.

Regarding claims 65, 74-75, 77-79, 81, 91-93, Park discloses (paragraph 0068) "a programmable processor (560) is contained in the housing (540) and controls the various modes of stimulation therapy." The examiner considers this to teach a computer readable medium capable of performing the actions claimed, in the above-cited paragraphs.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 8, 11, 13, 16, 26-27, 40-41 and 69-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (U.S. 2003/0153954) in view of Mika et al

(U.S. 6,459,928). Regarding claims 8, 26, 40 and 69-70, Park fails to teach the use of non-excitatory electrical stimulation and cardiac contractility modulation. Mika however discloses (column 2, lines 62-68; column 3, lines 1-2) a device that "has circuitry adapted for sensing and detecting cardiac depolarization events using one or more of the applied electrodes and for delivering non-excitatory ETC (excitable tissue controller) signals to the heart. In accordance with another preferred embodiment of the present invention, the device may also include circuitry for delivering pacing pulses to one or more sites of the patients heart." Though Mika remains silent on the use of non-excitatory stimulation of the heart as it relates to sleep-disordered breathing treatment, both Mika and Park teach devices and methods for modulating cardiac muscle activity to treat conditions. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Park's overdrive treatment with Mika's non-excitatory ETC in order to determine the proper timing of therapy taking into account capture of the heart.

Regarding claims 11, 13 and 16, Mika discloses (column 2, lines 51-61) "applying of electrodes to a first cardiac site and a second cardiac site of the patient." In one embodiment, the "first cardiac site is in or about the right atrium of the heart and the second cardiac site is in or about the left ventricle of the heart." The examiner considers this to be a stimulation module that provides atrial pacing coupled with the augmentation therapy. The atrial pacing is atrial coordinated pacing.

Regarding claims 27 and 41, Park discloses (paragraph 0042) "the cardiac stimulation device may prevent sleep apnea using a tiered therapy including an

elevated pacing rate stage, a resynchronization stage, and a dynamic overdrive stage." The examiner considers this to teach augmentation therapy delivered along with AOP.

10. Claims 9, 28-30, 37-39 and 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (U.S. 2003/0153954) in view of Bennett et al (U.S. 5,213,098). Regarding claims 9 and 28, Park fails to teach using PESP as augmentation therapy. Bennett however discloses (column 4, lines 14-23) providing "PESP and its electro-augmentation effects as an acute therapy for patients with acutely compromised cardiac function from disease, surgery, or other traumatic insult to the myocardium, including myocardial infarction on a periodic basis, wherein the periodicity of application of stimulation is controlled as a function of one or more physiologic parameters of the cardiovascular system." Bennett and Park both teach treatment of patients with cardiac arrhythmias in response to physiological parameters. Therefore it would have obvious to one of ordinary skill in the art at the time of the invention to modify Park's overdrive therapy with Bennett's PESP in order to optimize cardiac performance in patients diagnosed with sleep apnea.

Regarding claims 29-30, Park discloses (paragraphs 0057-0058) "in one example, intervention treats the sleep apnea condition by dynamic overdrive pacing. Referring to FIG. 4, a stimulation device (410) electrically couples to a patient's heart (412) using three leads (420, 424, and 430) to electrically communicate signals suitable for delivering multiple-chamber stimulation and shock therapy. The stimulation device couples to an implantable right atrial lead (420) having at least an atrial tip electrode

(422) to sense atrial cardiac signals and to supply right atrial chamber stimulation therapy."

Regarding claims 37-39, in view of the structure as disclosed by Park in view of Bennett, the method of operating or using the device would obvious because it is the normal and logical means by which the device can be used.

Regarding claims 66-68, Park discloses (paragraph 0068) "a programmable processor (560) is contained in the housing (540) and controls the various modes of stimulation therapy." The examiner considers this to teach a computer readable medium capable of performing the actions claimed, in the above-cited paragraphs.

11. Claims 10, 31-33, 42-44 and 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (U.S. 2003/0153954) in view of Mika et al (U.S. 6,459,928) in further view of Bennett et al (U.S. 5,213,098). Park in view of Mika fails to disclose using PESP as augmentation therapy. It would have been obvious to one of ordinary skill in the art to modify Park's tiered therapy with Mika's ETC signals to the heart and Bennett's PESP therapy in order to optimize cardiac performance in patients diagnosed with sleep apnea by using a variety of treatment options.

Allowable Subject Matter

12. Claims 18-22, 51, 53-61, 80 and 82-90 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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